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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/519,892	12/29/2004	Tetsuya Sakata	10921.267USWO	9700

7590  
Douglas P Mueller  
Merchant & Gould  
3200 Ids Center  
80 South 8th Street  
Minneapolis, MN 55402-2215

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EXAMINER

NAQI, SHARICK

ART UNIT

PAPER NUMBER

3736

SHORTENED STATUTORY PERIOD OF RESPONSE	MAIL DATE	DELIVERY MODE
3 MONTHS	01/18/2007	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

If NO period for reply is specified above, the maximum statutory period will apply and will expire 6 MONTHS from the mailing date of this communication.

<b>Office Action Summary</b>	<b>Application No.</b>		<b>Applicant(s)</b>	
	10/519,892		SAKATA ET AL.	
	<b>Examiner</b>		<b>Art Unit</b>	
	Sharick Naqi		3736	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☐ Responsive to communication(s) filed on \_\_\_\_.
- 2a) ☐ This action is **FINAL**.                      2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 1-28 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-15 and 20-28 is/are rejected.
- 7) ☒ Claim(s) 16-19 is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☒ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All    b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

- |  |   |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)            | 4) <input type="checkbox"/> Interview Summary (PTO-413)           |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)   | Paper No(s)/Mail Date. ____.                                      |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date <u>12/29/2004</u> .  | 6) <input type="checkbox"/> Other: ____.                          |

## **DETAILED ACTION**

### ***Specification***

1. The disclosure is objected to because of the following informalities:
2. On page 26, line 24 defines element 3 as a lancet holder. However, in the rest of the specification element 3 is defined as a sensor holder.
3. On page 3, line 13 defines element 91B as the second housing. However, line 13 on page 4 defines element 91B as the first case.

Appropriate correction is required.

### ***Claim Objections***

4. Claim 26 objected to because of the following informalities:  
  
In claim 26, it states, "The lancing apparatus according to claim 21, wherein the holding portion allows movement of the auxiliary part in a direction opposite from the first direction when the auxiliary part receives a force in said direction." Claim 21 refers to a first and a second direction. It is unclear what direction 'said direction' refers to in the claim. For the purpose of examination, the examiner has determined 'said direction' to mean a direction opposite the first direction.  
  
Appropriate correction is required.

### ***Claim Rejections - 35 USC § 102***

5. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

6. Claims 1, 3-15, 20, 21 and 25 rejected under 35 U.S.C. 102(b) as being anticipated by Lange et al. (United States Patent No. 5,554,166).

In regards to claim 1, Lange et al. disclose, a lancing unit (figure 1, element 3) comprising a lancing member (figure 1, element 4), an auxiliary part (figure 1, element 5) which is separate from the lancing member, and a supporter (figure 1, element 9) detachably supporting each of the lancing member and the auxiliary part (column 4, lines 24-34). Note that the supporter supports both the lancing member and auxiliary part as they are detachably connected to each other and the auxiliary part is attached to the supporter.

In regards to claim 3, Lange et al. disclose that when lancing of a skin is performed by utilizing the lancing member, the auxiliary part (figure 1, element 5) engages the lancing member (figure 1, element 4) to control lancing depth in the skin. Note that figure 1 shows that the auxiliary part would prevent the lancing member from advancing deeper into the skin.

In regards to claim 4, Lange et al. disclose that the lancing member includes a needle (figure 2, element 33), and wherein the lancing unit further comprises a cap for covering

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the needle (figures 1 & 2, element 7), the cap being detachable from the lancing member (column 3, lines 31-34).

In regards to claim 5, Lange et al disclose that the lancing member includes a body holding the needle (figure 1, element 31), and wherein the cap is integrally formed on the body (figures 1 & 2, element 7, and column 6, lines 12-17).

In regards to claim 6, Lange et al disclose a boundary portion (figure 2, element 51) between the cap and the body has a structure which causes a stress to be concentrated on the boundary portion more than on other portions of the cap and the body (column 6, lines 12-17). Note that the boundary portion has a thin walled structure which breaks what the cap is twisted.

In regards to claim 7, Lange et al disclose that the boundary portion has a constricted configuration (figure 2, element 51).

In regards to claim 8, Lange et al disclose that the lancing member is supported by the supporter via the cap (column 6, line 34-56). Note that when the lancing unit is inserted into the lancet holder, the engaging elements of the auxiliary part are supported by the supporter and since the auxiliary part is detachably connected to the lancing member via the cap, the supporter supports the auxiliary member via the cap.

In regards to claim 9, Lange et al disclose that the cap is formed separately from the supporter (figures 1 & 2) and supported by the supporter (column 6, line 34-56). Note that when the lancing unit is inserted into the lancet holder, the engaging elements of the auxiliary part are supported by the supporter and since the auxiliary part is detachably connected to the cap, the supporter supports the cap.

In regards to claim 10, Lange et al disclose that the supporter includes a portion for fitting to a part of the cap to hold the cap in a standing posture (column 5, lines 59-67, and column 6, lines 7-18). Note that the supporter has a portion that fits to the auxiliary part to hold it and the auxiliary part is detachably connected to the cap and so that holds the cap in a standing posture as seen in figure 1.

In regards to claim 11, Lange et al disclose that the cap is integrally formed on the supporter (column 5, lines 59-67, and column 6, lines 7-18). Note that the supporter is connected to the auxiliary part which is in turn connected to the cap. "Integral" is not necessarily restricted to one-piece article. – In re Kohno (CCPA) 157 USPQ 275.

In regards to claim 12, Lange et al disclose that the supporter comprises a case including a tubular portion at least one end of which is open, and wherein the case accommodates the lancing member, the cap, and the auxiliary part (figure 1). Note that the supporter has a tubular shape into which the cap, auxiliary part and lancet fit. The

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auxiliary part and the cap cover the smaller open end of the supporter while the lancing apparatus (figure 1, element 1) covers the larger open end of the supporter.

In regards to claim 13, Lange et al disclose that the lancing unit further comprises a lid for closing the open end of the case (figure 1). Note that auxiliary part and the cap cover the smaller open end of the supporter while the lancing apparatus covers the larger open end of the supporter, thus acting like lids to close the open ends of the supporter.

In regards to claim 14, Lange et al disclose that the direction in which the auxiliary part is detachable from the supporter (figure 1, and column 8, lines 1-5) corresponds to a direction in which the cap is detachable from the lancing member (figure 1, column 6, lines, lines 59-67, and column 7, lines 1-16). Note that after twisting the cap to break it off, the cap is removed in the same direction as that in which the auxiliary part is discarded.

In regards to claim 15, Lange et al disclose that the auxiliary part is detachably supported by the cap (figure 2 and column 6, lines 7-12).

In regards to claim 20, Lange et al disclose a lancing apparatus (figure 1, element 1) for performing lancing by utilizing a lancing unit (figure 1, element 3) including a lancing member (figure 1, element 4), an auxiliary part (figure 1, element 5) and a supporter (figure 1, element 9) detachably supporting the lancing member and the auxiliary part

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(column 4, lines 24-34), the apparatus comprising: a first holder for holding the lancing member (figure 1, element 11); a moving mechanism for advancing the first holder in a predetermined direction when a predetermined operation is performed (figure 1, element 12, column 4, lines 34-67, and column 5, lines 1-5) ; and a second holder for holding the auxiliary part when the lancing member is held by the first holder (column 6, lines 18-34). Note that the supporter supports both the lancing member and auxiliary part as they are detachably connected to each other and the auxiliary part is attached to the supporter. The lancing apparatus, as seen in figure 1, holds the supporter, so when the lancing member is held by the first holder, the auxiliary part is held by the lancing apparatus via the supporter.

In regards to claim 21, Lange et al disclose a lancing apparatus (figure 1, element 1) comprising: a moving mechanism (figure 1, elements 11 and 12) for holding a lancing member (figure 1, element 4) and advancing the lancing member in a first direction (column 4, lines 34-67, and column 5, lines 1-5); and a holding portion for arranging and holding an auxiliary part (figure 1, element 5) at a position spaced from a path of the advancing movement of the lancing member in a second direction crossing the first direction (column 6, lines 18-34); wherein at least one of the auxiliary part and the lancing member is movable in the second direction (figure 1, and column 8, lines 1-5). Note that the supporter supports both the lancing member and auxiliary part as they are detachably connected to each other and the auxiliary part is attached to the supporter. The lancing apparatus, as seen in figure 1, holds the supporter, so when the lancing



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member is held by the first holder, the auxiliary part is held by the lancing apparatus via the supporter. The space in the center of the auxiliary part places it at a position spaced from a path of the advancing member in a second direction. Additionally, since the lancing member and auxiliary part are removable they are both movable in the second direction.

In regards to claim 25, Lange et al disclose that when the lancing member (figure 1, element 4) advances, the lancing member engages the auxiliary part (figure 1, element 5) so that the advancing movement of the lancing member is controlled. Note that figure 1 shows that the auxiliary part would prevent the lancing member from advancing deeper into the skin.

7. Claims 1, 2, 21, 22, 27 and 28 rejected under 35 U.S.C. 102(b) as being anticipated by Uchigaki et al. (PCT Pub. No. WO01/41643, US Patent No. 6,849,052 is the 371 of the PCT and has been used as a certified translation so the column and line numbers correspond to the US Patent).

In regards to claim 1, Uchigaki et al disclose a lancing unit comprising a lancing member (figure 2, element 31), an auxiliary part (figure 2, element 36) which is separate from the lancing member, and a supporter (figure 2, element 20) detachably supporting each of the lancing member and the auxiliary part (column 4, lines 49-59).

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In regards to claim 2, Uchigaki et al disclose that the auxiliary part comprises a part for taking a sample obtained by lancing (figures 2-4, element 36, and column 7, lines 57-67).

In regards to claim 21, Uchigaki et al disclose a lancing apparatus (figure 2) comprising: a moving mechanism (figure 2, elements 23, 30 and 32) for holding a lancing member (figure 2, element 31) and advancing the lancing member in a first direction (figures 2-4); and a holding portion for arranging and holding an auxiliary part (figure 2, element 36) at a position spaced from a path of the advancing movement of the lancing member in a second direction crossing the first direction (figures 2-4); wherein at least one of the auxiliary part and the lancing member is movable in the second direction (figures 2-4). Note that the auxiliary part is movable in the second direction as indicated by the arrow in figure 4.

In regards to claim 22, Uchigaki et al disclose that the holding portion is capable of moving the auxiliary part in the second direction (figures 2-4). Note that the auxiliary part is moved forward as indicated by the arrow in figure 4.

In regards to claim 27, Uchigaki et al disclose the lancing apparatus further comprising a measurement probe, wherein the auxiliary part includes an electrode for analyzing a sample obtained by lancing; and wherein the measurement probe is brought into contact with the electrode as a result of movement of the auxiliary part toward the

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advancing movement path of the lancing member (column 8, lines 27-67, and column 9, lines 1-13).

In regards to claim 28, Uchigaki et al disclose the lancing apparatus further comprising a control circuit for executing analysis of the sample (column 7, lines 6-14).

8. Claims 21, 23 and 24 rejected under 35 U.S.C. 102(b) as being anticipated by Schraga (United States Patent No. 5,797,942).

In regards to claim 21, Schraga discloses a lancing apparatus comprising: a moving mechanism (figures 1-7B, element 120) for holding a lancing member (figure 6A and 6B, element 60) and advancing the lancing member in a first direction; and a holding portion (figures 6A and 6B) for arranging and holding an auxiliary part (figures 6A and 6B, elements 30, 32 and 33) at a position spaced from a path of the advancing movement of the lancing member in a second direction crossing the first direction; wherein at least one of the auxiliary part and the lancing member is movable in the second direction (figures 6A and 6B). Note that figures 6A and 6B show that the auxiliary part is located next to the path of the advancing movement of the lancing member, and is movable in a direction crossing that path.

In regards to claim 23, Schraga discloses that the moving mechanism detachably holds the lancing member; and wherein a cap for covering a needle of the lancing member is

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attached to the lancing member (figure 2, element 62), the holding portion being capable of moving the auxiliary part toward the advancing movement path of the lancing member when the cap is separated from the lancing member with the lancing member held by the moving mechanism (figures 6A and 6B). Note that figure 2 shows that the cap covering the needle is removed. Figures 6A and 6B show that the auxiliary part is located next to the path of the advancing movement of the lancing member, and the holding portion is capable of moving the auxiliary member in a direction crossing that path.

In regards to claim 24, Schraga discloses that the holding portion includes a first wall (figure 6A and 6B, element 15), a second wall located closer to the advancing movement path of the lancing member than the first wall, a space defined between the first and the second walls into which the auxiliary part can be partially inserted movably in the second direction, and a resilient member (figure 6A and 6B, element 33) for pressing a portion of the auxiliary part toward the second wall when the auxiliary part is partially inserted into the space. Note the figures 6A and 6B show that the auxiliary part is in a space between the first wall and the side of the moving mechanism that acts as a second wall. The resilient member pushes the auxiliary part towards the second wall as can be seen in figure 6B.

9. Claims 21 and 26 rejected under 35 U.S.C. 102(b) as being anticipated by Slama (United States Patent No.4,469,110).

In regards to claim 21, Slama discloses a lancing apparatus (figures 1-5) comprising: a moving mechanism (figure 1-4, element 3) for holding a lancing member (figures 1-5, element 1a) and advancing the lancing member in a first direction; and a holding portion (figures 1-5, element 2a) for arranging and holding an auxiliary part (figures 1-5, element 5a) at a position spaced from a path of the advancing movement of the lancing member in a second direction crossing the first direction; wherein at least one of the auxiliary part and the lancing member is movable in the second direction. Note that in figure 3, the auxiliary part is in a position spaced from the path of the advancing movement of the lancing member in a second direction crossing the first. The shape of the holding portion allows the auxiliary part to be movable in the second direction.

In regards to claim 26, Slama discloses that the holding portion allows movement of the auxiliary part in a direction opposite from the first direction when the auxiliary part receives a force in said direction (figures 1-5). Note that the shape of the holding portion allows the auxiliary part to be moved in the first direction when it receives a force in the first direction and a direction opposite the first direction when it receives a force opposite the first direction.

***Allowable Subject Matter***

10. Claims 16-19 are objected to based on their dependence on a rejected claim, but would be allowable if rewritten to overcome the prior art rejection(s) set forth in this Office action and to include all of the limitations of the base claim and any intervening

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claims. In regards to claim 16, the limitation "wherein the cap is supported by the supporter while being interposed between the lancing member and the auxiliary part in a first direction in which the needle of the lancing member extends, the cap being movable in a second direction crossing the first direction to avoid overlapping with the auxiliary part in the first direction" is not found in the prior art. Claims 17-19 are allowable based on their dependency on claim 16.

Any comments considered necessary by applicant must be submitted no later than the payment of the issue fee and, to avoid processing delays, should preferably accompany the issue fee. Such submissions should be clearly labeled "Comments on Statement of Reasons for Allowance."

### ***Conclusion***

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Sharick Naqi whose telephone number is 571-272-3041.


The examiner can normally be reached on 8:30 am - 5:00 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Max Hindenburg can be reached on 571-272-4726. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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SN



Michael Asorano